Phase I Project Summary

Firm: CFD Research Corporation
Contract Number: NNX12CG02P
Project Title: An Electrochemical, Point-of-Care Detector for Reagent-free, In-situ Diagnostics of Pathogens

Identification and Significance of Innovation:

For long-term exploratory space travel, there will be a critical need for *in-situ* diagnosis and assessment of biological specimens from symptomatic astronauts, especially disease pathogens (virus, bacteria, or fungus) and microbial contaminants. A real-time, non-culture-based microbial identification and quantification system for on-flight monitoring of pathogens from astronauts, or the space environment, is strongly desired. To meet this need, we proposed to develop a novel miniaturized, point-of-care (POC) detector for direct, reagent-free, *in-situ* diagnostics of disease pathogens. The electrochemical probe methodology is based on several innovations, which make in-situ, reagent-free, rapid direct diagnosis of pathogen from biological samples possible, without the need for complicated sample purification procedures, exogenous labels, or expensive, heavy, power-hungry instrumentation. To our best knowledge, there is no rapid and accurate sensor device that can be deployed during space exploration for pathogen diagnosis, especially for real-time biological samples. The end product of the proposed STTR effort will meet the need as a first-of-kind, commercially available, compact, low-cost, integrated disease pathogen analysis device. Moreover, this research will provide a versatile platform to monitor other biological interactions in many biochemical processes, which will greatly enhance the ability of scientists and engineers to conduct both fundamental and applied research.

Technical Objectives and Work Plan:

The overall objective of this STTR effort will be a hand-held, electrochemical POC detector for reagent-free, in-situ diagnostics of pathogens. The system will consist of a reusable and replaceable electrochemical probe along with required data collection electronics, and data processor, which will have a modular design that is adaptable to prevalent “smart” device for data communication. Our Phase I goal is to demonstrate proof-of-concept of the proposed electrochemical detector probe, and the effort will focus on the synthesis of electro-active molecule, the preparation of electrochemical electrode and detection of a pathogen, *E. coli*. The feasibility of using a new electrochemical probe at solid electrodes for selective diagnosis of disease pathogens will be proven. Specifically, the following areas will be studied: (1) design and synthesis of electro-active molecules; (2) fabrication and construction of electrochemical probe at solid electrodes; (3) evaluation of sensing signal transduction and verification of the detection principle; (4) demonstration of *in-vitro* detection of pathogens; and (5) documentation review and reporting. At the end of Phase I, we will have proven the concept (TRL2-3) and be at a stage for improvement, optimization, fabrication and integration of devices in future.

Technical Accomplishments:

The Phase 1 studies have clearly demonstrated the utility and value of the two approaches for effective electrochemical probes to detect carbohydrate-lectin interactions as well as proof-of-concept pathogen detection from aqueous samples. In the Phase I effort, the proposed signal transduction was verified and a new series of electro-active probes were demonstrated for direct, selective, ultrasensitive *in-vitro* detection of a model bacterium. The technology is adaptable for sensor probes to detect real pathogenic bacteria. Specific accomplishments are listed as follows:

- Successful design and synthesis of molecules
- Successful construction of electrochemical probe
- ***Glycosylated polyaniline*** electrode has been developed as an effective platform to study carbohydrate–protein interactions based on the extremely high sensitivity of polyaniline to the local proton exchange.
- ***A two-component-SAM ECR electrode*** was developed and proven to provide signal amplification after the lectin binding to monose-tethered to the SAM, effective to a larger range of lectin concentrations
- Proof-of-concept demonstration the lowest detection limit of 100 counts/mL E.Coli in aqueous samples by using both the mannose PANI electrode probe and the two component-SAM electrode probe with a sensitive response for bacteria in the range of 10^2 to 10^6 count/mL.
- Achieved technology currently at TRL: 2-3

NASA Application(s):

The end product of the proposed STTR effort will be a first-of-a-kind, commercially available, compact, low-cost, integrated disease pathogen analysis device without need of cell-culturing. NASA will have a handheld, easy-to-use electrochemical pathogen detector that can be easily integrated with existing astrobiological instrumentation and/or emerging smart biomedical system to keep track of astronaut health and space environment during planetary exploration. In addition, the same device can be adapted and used in other applications, such as life discovery on other planets, pharmacotherapy environment monitoring, and space biology experiments.

Non-NASA Commercial Application(s):

The platform developed in this effort will provide the technological backbone to develop a new type of electrochemical sensor or diagnostic technology and no-cell-culturing-based pathogen detection for applications in healthcare, life sciences, hospital and health site monitoring. This platform will enable the creation of *in-situ* analytical tools for the preparation, detection, and analysis of low level pathogens obtained from biological fluid and/or water samples. It may find use in drug discovery, foodborne pathogens, environmental monitoring, and the study of human diseases, clinical and preclinical diagnosis, as well as in the areas of cellular biology, microbiology, and homeland security.

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